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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,562	04/20/2001	Troy Wilford	8932-268	1273
20583	7590	12/11/2003	EXAMINER	
PENNIE AND EDMONDS 1155 AVENUE OF THE AMERICAS NEW YORK, NY 100362711			KOKABI, AZADEH	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 12/11/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,562

Applicant(s)

WILFORD, TROY

Examiner

Azy Kokabi

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,6,16 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7-11,17-20 and 24-32 is/are rejected.
- 7) ☒ Claim(s) 12-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 3743

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 3, 5, 24-32, 25, 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg

Rosenberg et al disclose a ligament reconstruction graft anchor apparatus with an implant body (figure 2, #22) having a first and second end (figure 2, #36 and 34). Rosenberg discloses a first end of the implant body (figure 2, #34) in which an insertion tools is received through (see figure 3, #60). Further, Rosenberg discloses a second end (figure 2, #34) in which the coupling member is attached to (figure 2, #36).

Rosenberg also discloses a graft interface member (figure 2, #20) having a graft holding portion (figure 2, #50) and an implant coupling portion (figure 2, #48). The implant body is able to rotate independently of the graft interface member (column 5, lines 46-49). Further, the graft

Art Unit: 3743

holding portion has a central longitudinal axis (figure 3, #4) that is adapted to hold a graft aligned with the central longitudinal axis as shown in figure 6.

Rosenberg, further, discloses a cage graft holding portion (see figure 2, #20). Rosenberg discloses a cage with a cage bottom below the hole (see figure 3, #50) and a cage top above the holes. The section in between the holes interconnects the top and the bottom cage portions. The cage portions are attached together through the section between the holes (see figure 3).

Further, Rosenberg discloses an implant body that is integrally connected to the graft interface member (see figure 2). Figure 2 discloses a hexagonal opening in the first end of the implant body (also see abstract). Rosenberg also discloses an implant body containing external threads (figure 2, #30).

Rosenberg, however, fails to show that the implant coupling portion is adapted to be received in the recess of the implant body. Instead, Rosenberg shows that the implant coupling portion is dimensioned to form a press fit or mating relationship with the trailing end of the implant body.

It would have been obvious to provided a recess to attach the implant coupling portion with the implant body because a recess, similar to a mating region perform adequate coupling functions.

Rosenberg also fails to show that the first end of the graft is attached to the graft interface portion along the central longitudinal axis. The graphs are attached to wall of the implant coupling portion, however, the graph is aligned at its central longitudinal axis when inserted into the body (see figures 5 and 6). Therefore, it would have been obvious to have provided the graft at the implant body's central axis since both devices attach the graft along the central

Art Unit: 3743

longitudinal axis once into the body. Therefore, the methods as recited would have been obvious in view of Rosenberg.

4. Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Hitomi ('267).

As previously, discussed in paragraph 3 above, further Rosenberg discloses all the limitations as set forth. Rosenberg also discloses a snap connection between the implant body and the graft interface member, however the annular flange is shown on the implant body and not on the coupling portion of the device.

Rosenberg does not disclose an implant coupling portion with a flexible post, slotted flared tip portion or an undercut section in the second opening of the implant body. Further, Rosenberg fails to disclose an implant body with internal thread portion.

Hitomi et al discloses a bone connector that is adapted to join cut bone ends. Hitomi discloses the connection means that is utilized in claims 7-10 to connect bone ends. Specifically, Hitomi discloses an implant coupling portion with a flexible post (figure 3a, #709) that has a flared tip portion (figure 3, #709). The flared tip portion is slotted (see figure 3). Further, Hitomi discloses an undercut section in the recess of the bone connector (figure 2A #511).

It would have been obvious to one of ordinary skill in the art to modify the snap fixation device of Rosenberg with the snap connection means in Hitomi in order to provide a more secure means to connect the implant body and the graft interface member. The attachment means of Hitomi provides a "snugly fitted" connection in the groove, which remains "elastically deformed" (see column 4, lines 25-26 and 30).

Art Unit: 3743

5. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Chauvin et al ('763).

As previously, discussed in paragraph 3 above, further Rosenberg discloses all the limitations as set forth, however, Rosenberg does not disclose an internally threaded implant body.

Chauvin discloses an expandable osteosynthesis cage, which includes an internally threaded implant body. The internal threads were employed to secure the spacer into the implant body (compare figure 1 and 2).

It would have been obvious to one of ordinary skill in the art to have modified the device in Rosenberg with the internally threaded implant body of Chauvin in order to facilitate a secure connection between the implant body and the graft interface member. Coupling the graft member with the implant body through the use of internal threads provides an efficient means to connect and disconnect the two devices as would have been obvious to one of ordinary skill in the art.

6. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Suddably ('244).

As previously, discussed in paragraph 3 above, further Rosenberg discloses all the limitations as set forth, however, Rosenberg fails to disclose a graft holding portion having two separate members which are configured to mate or snap together.

Suddably discloses an expandable implant, which has a cage comprising of two parts (#10 and #12). The two parts connect or are snapped with each other (see figure 2). This configuration provides a means to expand the implant body which is easy to manufacture and

Art Unit: 3743

simple to use in daily clinical surgical practice, while remaining versatile enough to address complex biologic and pathologic variability of the human spine.

Therefore, in view of Suddaby, it would have been obvious to have modified the singular piece cage portion of Rosenberg with the two member cage portion of Suddaby in order to gain versatility when faced with complex variability during surgery.

Allowable Subject Matter

7. Claims **12-15** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments filed 09/22/03 have been fully considered but they are not persuasive. Applicant argues that Rosenberg fails to disclose, teach, or suggest a fixation device having an implant coupling portion. However, Rosenberg discloses an implant body (#22) and a graft interface member (#20). These two structures are attached or coupled together via an "implant coupling portion" (see generally figure 2, #48). The implant body is preferably welded (Rosenberg; 3:55) with an insert member (#18) which is fitted into the implant body and couples the body with the graft interface member. The graft interface member is allowed to rotate freely relative to the insert member (Rosenberg, 4:17-20). Although Rosenberg teaches a snap-fit connection, it would have been obvious to one of ordinary skill in the art to have provided for a recess-typed means of connection between the implant body and the graft interface member because the use of a recess connection means in lieu of those used in the Rosenberg reference

Art Unit: 3743

solves no stated problem nor does it provide an advantage. Therefore, the form of connection used to connect the implant body with the graft interface member is a matter of design choice.

Applicant further argues that reference number 36 of the Rosenberg reference is the first end of the implant body. However, claim 1 broadly recites "the first end having an opening configured and adapted to receive an insertion tool and the second end having a recess."

Rosenberg discloses a first end (#34) having an opening in which an insertion tool is adapted to be received through and a second end (#36) having a recess. Therefore, the first and second ends of the implant body are taught by the Rosenberg device.

Applicant further argues that Rosenberg fails to disclose a graft holding portion.

Applicant argues that providing the graft at the implant body's central axis where the implant of Rosenberg is designed to receive the driver would block the access of the driving tool and increase the likelihood of damaging the grafts during insertion into the joint as the result of interference from the driver (page 4). However, Rosenberg teaches that the grafts are positioned and held firmly around the shaft of the driver (#64) which is aligned with the central longitudinal axis (Rosenberg, 4: 39-42).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Although Greenfield ('835) and DiPoto ('953) are not relied upon by Examiner as grounds for rejection, these references, as cited in Applicant Information Disclosure Statement, show a graft interface member that is connected to an implant body through a recess.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3743

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Azy Kokabi whose telephone number is (703) 306-4154. The examiner can normally be reached on Monday- Friday, 6:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

AK

Henry Bennett
Supervisory Patent Examiner
(703) 308-0101

